DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP 11 2005

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Nayan Raval, V.P.
Silarx Pharmaceuticals, Inc.
19 West Street
Spring Valley, NY 10977

Re: Docket No. 2005P-0096/CP1

Dear Mr. Raval:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on March 7, 2005. Your petition requests that the Agency allow Silarx Pharmaceuticals, Inc. (Silarx) to reference Schering-Plough's Claritin Hives Relief syrup, which is listed as a discontinued product in the Orange Book, as a Reference Listed Drug Product in Silarx's abbreviated new drug application (ANDA) 77-421 for Loratadine Syrup – Hives Relief.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

CC: Ash Tankha, Esq.
36 Greenleigh Drive
Sewell, NJ 08080

2005P-0096

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